



PATENT  
Docket No. 275.0009 0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): MUNN et al. ) Group Art Unit: 1614  
Serial No.: 10/780,150 )  
Confirmation No.: 1273 )  
Filed: February 17, 2004 )  
For: REGULATION OF T CELL-MEDIATED IMMUNITY BY D ISOMERS OF  
INHIBITORS OF INDOLEAMINE-2,3-DIOXYGENASE

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form is respectfully requested. Pursuant to the provisions of M.P.E.P. § 609, Applicants further request that a copy of the 1449 form, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to:  
**Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 1 day of MAY, 2007.

Name: Sandy Truhart  
\_\_\_\_\_  
Sandy Truhart

Date May 1, 2007

Respectfully submitted for  
MUNN et al.  
By  
Mueting, Raasch & Gebhardt, P.A.  
P.O. Box 581415  
Minneapolis, MN 55458-1415  
Phone: (612)305-1220  
Facsimile: (612)305-1228  
**Customer Number 26813**

By: Nancy A. Johnson  
\_\_\_\_\_  
Nancy A. Johnson  
Reg. No. 47,266  
Direct Dial (612)305-4723

**INFORMATION  
DISCLOSURE  
STATEMENT**

MAY 03 2007

PATENT & TRADEMARK OFFICE

Atty. Docket No.: 275.0009 0101	Serial No.: 10/780,150
Applicant(s): MUNN et al.	Confirmation No.: 1273
Application Filing Date: 02/17/04	Group: 1614
Information Disclosure Statement mailed:	May 1, 2007

**U.S. PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,244,946	01/13/81	Rivier et al.			
		4,305,872	12/15/81	Johnston et al.			
		4,316,891	02/23/82	Guillemin et al.			
		4,629,784	12/16/86	Stammer			
		4,792,525	12/20/88	Ruoslahti et al.			
		4,868,116	09/19/89	Morgan et al.			
		4,980,286	12/25/90	Morgan et al.			
		5,244,807	09/14/93	Murtfeldt et al.			
		5,723,325	03/03/98	Murtfeldt et al.			
		5,874,560	02/23/99	Kawakami et al.			
		2003/0194803	10/16/03	Mellor			
		2004/0161425	08/19/04	Munn			
		2004/0234623	11/25/04	Munn			
		2005/0186289	08/25/05	Munn			
		2006/0292618	12/28/06	Mellor			
		2007/0048769	03/01/07	Mellor			
		2007/0077234 A1	04/05/07	Munn et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	✓	WO 2000/66764	11/9/00	PCT				
	✓	0 385 385 A2	09/05/90	Europe				
	✓	WO 93/01286	01/21/93	PCT				

**EXAMINER****Date Considered**

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	<input checked="" type="checkbox"/>	WO 1998/25840		PCT				
	<input checked="" type="checkbox"/>	WO 2006/040796	10/20/06	PCT				
	<input checked="" type="checkbox"/>	WO 2007/000404	01/05/07	PCT				

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copy Enclosed	Document Description
	<input checked="" type="checkbox"/>	Burke et al., "The role of indoleamine 2,3-dioxygenase in the anti-tumor activity of human interferon-gamma in vivo", <i>Int. J. Cancer</i> , 60(1):115-122 (1995).
	<input checked="" type="checkbox"/>	Cady et al., "1-Methyl-DL-tryptophan, $\beta$ -(3-Benzofuranyl)-DL-alanine (the Oxygen Analog of Tryptophan), and $\beta$ -[3-Benzo(b)thienyl]-DL-alanine (the Sulfur Analog of Tryptophan) Are Competitive Inhibitors for Indoleamine 2,3-Dioxygenase", <i>Arch. Biochem. Biophys.</i> , 291(2):326-333 (1991).
	<input checked="" type="checkbox"/>	Gura, "Systems for Identifying New Drugs are Often Faulty," <i>Science</i> , 1997, 278:1041-1042.
	<input checked="" type="checkbox"/>	Habara-Ohkubo et al., "Cloning and expression of a cDNA encoding mouse indoleamine 2,3-dioxygenase", <i>Gene</i> , 105(2):221-227 (1991).
	<input checked="" type="checkbox"/>	Johnson et al., "Relationships between drug activity in NCI preclinical in vitro and in vivo models and early clinical trials," <i>British Journal of Cancer</i> , 2001, 84(10):1424-1431.
	<input checked="" type="checkbox"/>	Kadoya et al., "Gene structure of human indoleamine 2,3-dioxygenase," <i>Bio. and Biophysical Research Comm.</i> 1992, Vol.189, No. 1 pp.530-536
	<input checked="" type="checkbox"/>	Li et al., "Expression of indoleamine 2,3-dioxygenase in dermal fibroblasts functions as a local immunosuppressive factor," <i>J. Invest. Dermatol.</i> 2004, 122(4):953-964
	<input checked="" type="checkbox"/>	Meyer et al., "Trptophan metabolism in chronic inflammatory lung disease", <i>J. Lab. Clin. Med.</i> ,126(6):530-540 (1995).
	<input checked="" type="checkbox"/>	Miki et al., Abstract # 714, "Indoleamine 2, 3- Dioxygenase Blockade Prevents Spontaneous Liver Allograft Tolerogenicity in the Mouse", <i>Transplantation®</i> , 69(8):S297 (2000).

<b>EXAMINER</b>	<b>Date Considered</b>
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	✓	Muller et al., "Indoleamine 2,3-dioxygenase in cancer: targeting pathological immune tolerance with small-molecule inhibitors," <i>Expert Opinion Ther. Targets</i> , 2005, 9(4):831-849.
	✓	Munn, David H., "Regulation of Macrophage Apoptosis," Grant Abstract, Grant Number 1K08HL03395-01 [online]. National Institutes of General Medical Sciences, National Institutes of Health, project dates 07/01/95-06/30/98 [retrieved on 2001-02-15]. Retrieved from the Internet: URL: <a href="http://commons.cit.nih.gov/crisp_historical/crisp_lib.getdoc?textkey=2211646&amp;p_grant_num=1K08HL03395-01&amp;p_query=&amp;ticket=63957&amp;p_audit_session_id=363938&amp;p_keywords=&gt;, 2 pages.">http://commons.cit.nih.gov/crisp_historical/crisp_lib.getdoc?textkey=2211646&amp;p_grant_num=1K08HL03395-01&amp;p_query=&amp;ticket=63957&amp;p_audit_session_id=363938&amp;p_keywords=&gt;, 2 pages.</a>
	✓	Munn, David H., "Inhibition of T Cells by Tryptophan Degradation," Grant Abstract, Grant Number 1R21AI44759-01 [online]. National Institutes of General Medical Sciences, National Institutes of Health, project dates 09/30/98-009/29/00 [retrieved on 2001-02-15]. Retrieved from the Internet: URL: <a href="http://commons.cit.nih.gov/crisp_historical/crisp_lib.getdoc?textkey=2802812&amp;p_grant_num=1R21AI44759-01&amp;p_query=&amp;ticket=63957&amp;p_audit_session_id=363938&amp;p_keywords=&gt;, 2 pages.">http://commons.cit.nih.gov/crisp_historical/crisp_lib.getdoc?textkey=2802812&amp;p_grant_num=1R21AI44759-01&amp;p_query=&amp;ticket=63957&amp;p_audit_session_id=363938&amp;p_keywords=&gt;, 2 pages.</a>
	✓	Munn, David H., "Macrophage Mediated Immunoregulation Via Tryptophan," Grant Abstract, Grant Number 5R01HL60137-03 [online]. National Institutes of General Medical Sciences, National Institutes of Health, project dates 01/01/99-12/31/02 [retrieved on 2001-02-15]. Retrieved from the Internet: URL: <a href="http://commons.cit.nih.gov/crisp_lib.getdoc?textkey=6343616&amp;p_query=&amp;ticket=1890054&amp;p_audit_session_id=3588259&amp;p_keywords=&gt;, 2 pages.">http://commons.cit.nih.gov/crisp_lib.getdoc?textkey=6343616&amp;p_query=&amp;ticket=1890054&amp;p_audit_session_id=3588259&amp;p_keywords=&gt;, 2 pages.</a>
	✓	Munn, "Indoleamine 2,3-dioxygenase, tumor-induced tolerance and counter-regulation," <i>Curr. Opin. Immunol.</i> 2006 Apr;18(2):220-225. Epub 2006 Feb 7.
	✓	Ozaki et al., "Induction of indoleamine 2,3-dioxygenase: A mechanism of the antitumor activity of interferon $\gamma$ ", <i>Proc. Natl. Acad. Sci. USA</i> , 85:1242-1246 (1988).

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	✓	Peterson et al., "Evaluation of Functionalized Tryptophan Derivatives and Related Compounds as Competitive Inhibitors of Indoleamine 2,3-Dioxygenase", <i>Med. Chem. Res.</i> , 3:531-544 (1994).
	✓	Potula et al., Inhibition of indoleamine 2,3-dioxygenase (IDO) enhances elimination of virus-infected macrophages in an animal model of HIV-1 encephalitis," <i>Immunobiology, Blood</i> , 1 October 2005, 106(7):233822390.
	✓	Raynovich, "Late-Stage Cancer Vaccines Set to Launch, with Five Major Players, Therapeutic Vaccines Could Transform Medical Care," <i>GEN Biobusiness Wall Street Biobeat</i> . March 1, 2007. genengnews.com. <i>Gen. Eng. &amp; Biotech. News</i> .
	✓	"Rheumatoid Arthritis," <i>Genetic Eng. &amp; Biotech. News</i> , March 1, 2007. Genengnews.com , (72) Translational Medicine.
	✓	Romani et al., "Generation of mature dendritic cells from human blood: An improved method with special regard to clinical applicability," <i>J. Immunol. Methods</i> , 1996;196:137-151.
	✓	Sarkhosh et al., "Immune cell proliferation is suppressed by the interferon-gamma-induced indoleamine 2,3-dioxygenase expression of fibroblasts populated in collagen gel (FPGG)," <i>J. Cell Biochem</i> . 2003, 1;90(1):206-217
	✓	Sono et al., "Indoleamine 2,3-Dioxygenase. Equilibrium Studies of the Tryptophan Binding to the Ferric, Ferrous, and Co-Bound Enzymes", <i>J. Biol. Chem.</i> , 255(4):1339-1345 (1980).
	✓	Steckel et al., "Indoleamine 2,3-Dioxygenase expression in patients with acute graft-versus-host disease after allogeneic stem cell transplantation and in pregnant women: association with the induction of allogeneic immune tolerance?", 2003, <i>Scandinavian Journ. Of Immun.</i> , 57, pp 185-191
	✓	Swanson et al., "CD11c+ Cells Modulate Pulmonary Immune Responses by Production of Indoleamine 2,3-Dioxygenase," 2004, <i>Am. Journ. Of Respiratory Cell and Molecular Biology</i> , Vol. 30, pp 311-318
	✓	Terness et al., "Inhibition of allogeneic T cell proliferation by Indoleamine 2,3-Dioxygenase-expressing dendritic cells: mediation of suppression by tryptophan metabolites," 2002, <i>J. Exp. Med.</i> Vol.196, No. 4, pp 447-457.

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